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EXAMINER	
LUM, LEON YUN BON	
ART UNIT	**PAPER NUMBER**
1641	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,728	SELVAN, GOWRI PYAPALI	
	Examiner	Art Unit	
	Leon Y Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 November 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: In regards to Figure 1A, the reference sign 128 points to two different channel types, including one labeled as reference sign 130. The specification defines reference sign 128 as describing "Fluidic circuits" (page 16, line 10) and is applicable to both types of channels it currently labels. However, in order to avoid confusing with reference sign 130, it is advised that the lines protruding from the number 128 do not touch the channels.

In regards to Figure 1A, reference signs 134 and 136 are duplicates since the specification defines both as "mixing chambers" (page 16, lines 7-8).

In regards to Figure 1B, reference sign 140 indicates "target zones" (page 16, line 22) on substrate 106, which is not shown in the figure. Only channel layer 104 is indicated.

In regards to Figure 1C, cap 100 on the left side of the disc seems to be on the same level as the unlabeled upper portion on the right side of the disc (portion including signs 122, 124, and 128). The unlabeled portion has channel-like structures, as shown in Figures 1A and 1B, with channel labels (reference sign 128) that indicate it is channel layer 104. However, channel layer 104 is shown to be beneath cap 102 on the left side

of the disc. Therefore, Figure 1C is confusing by depicting different disc layers in inconsistent locations.

In regards to Figure 2A, reference sign 150, which is described as indicating the transmissive optical disc with multiple layers and encompasses multiple layers (page 17, line 21) is misleading. It points directly to cap 152 and may be perceived as indicating only cap 152.

In regards to Figure 2C, cap 152 on the left side of the disc seems to be on the same level as the unlabeled upper portion on the right side of the disc (portion including sign 164). The unlabeled portion includes channel-like structures, as shown in Figures 2A and 2B, that indicate it is channel layer 154. However, channel layer 154 is shown to be beneath the cap 152 on the left side of the disc. The unlabeled portion also includes the reference signs 158 and 160 that refer to the cap 152, but the cap and channel layer are two different layers, as described (page 17, lines 21-26). Therefore, Figure 2C is confusing by depicting different disc layers in inconsistent locations with inconsistent reference signs.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

In regards to claims 6-7, the phrases "discrete capture zone" (line 2 of the claim 6) and "second discrete capture zones" (line 1 of claim 7) are not recited in the disclosure. The term "capture zone" is recited numerous times in the disclosure, but not with the limitation of "discrete". Appropriate correction is required.

In regards to claim 7 and 17, the term "capture agents" (line 2 of claims 7 and 17) is not disclosed in the specification when defining "a second discrete capture zone" (line 2 of claim 7) or a being in a "plurality of capture zones" (lines 1-2 of claim 17). The specification discloses a channel with multiple capture areas or zones with antibodies (page 5, line 26 to page 6, line 2). Although antibodies are one type of capture agent, the claims are broad in reciting capture "agents" and this limitation is not disclosed in the specification when defining a second discrete capture zone for claim 7 or referring to elements within a plurality of capture zones for claim 17.

In regards to claim 7, the term "predetermined pattern" (line 2 of the claim) is not disclosed in the specification and it is unclear how the pattern is portrayed.

In regards to claim 13, the phrase "determine a cell concentration" (line 2 of the claim) is not disclosed in the specification.

Claim Objections

3. Claim 7 is objected to because of the following informalities: the term "zones" in line 2 of the claim reads like it should be "zone". Appropriate correction is required.

4. Claim 16 is objected to because of the following informalities: the term "distinguished" in line 2 of the claim reads like it should be "distinguishes". Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1 and 4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. In claim 1, the terms "disc surface" (line 3 of the claim) and "disc" (line 5 of the claim) are unclear and indefinite. Are the discs the "optical disc" (line 1 of the claim) or the "disc drive" (lines 1-2 of the claim) recited in the preamble?

Also in claim 1, the term "optical disc" (line 6 of the claim) is unclear and indefinite. It is unclear whether the term refers to the "disc" recited above (line 5 of the claim) or to another optical disc.

Also in claim 1, the phrase "providing a sample of cells on a disc surface in a chamber in a disc" (lines 3-4 of the claim) is confusing and indefinite. Is the surface within the disc? The beginning of the phrase "providing a sample of cells on a disc surface in a chamber" implies that the cells are placed on top of the disc and enclosed within chamber. However, the latter part of the phrase "chamber in a disc" implies that the chamber is interior to the disc and would therefore require that the surface with the cells is also interior to the disc, which is not what is implied by reading the first part of the phrase. Applicant is invited to clarify exactly where the surface is located in relation to the chamber and disc.

In claim 5, the phrase "any one of claim 1" is confusing and indefinite. Is the part "any one" referring to specific steps within claim 1, or does it refer multiple claims that have been left out of claim 5?

8. Claim 4 recites the limitation "the detector" in line 4 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "the level of light reflected from or transmitted through the disc" in lines 2-3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 18 recites the limitation "the capture molecules" in line 3 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 recites the limitation "the captured cells" in lines 1-2 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1-9, 12-15, 17-18, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Sheppard, Jr. et al (USP 6,143,247).

Sheppard, Jr. et al anticipate the instant claims by teaching that a method where a sample is applied to a detection or cell accumulation chamber of a platforms (column 14, lines 6-7), wherein the term "platform" is intended to encompass any solid support structure providing a surface or comprising a chamber that can be treated to comprise a specific binding reagent (providing a sample of cells on a disc surface in a chamber in a

disc) (column 10, lines 15-18), and wherein the surface or detection chamber can be treated to provide a two-dimensional array or pattern, wherein certain areas on the surface or detection chamber are treated with said specific binding reagent and others are not in a recognizable manner (the chamber including at least one capture zone with a capture agent) (column 10, lines 59-64). In addition, Sheppard, Jr. et al also teach that the detection system can comprise a component of a device manipulating the platform, preferably comprising an optical detecting means (loading the disc into an optical reader) (column 14, lines 61-63) and that the disk can be loaded and spun (rotating the optical disc) (column 26, lines 55-56). In addition, Sheppard, Jr. et al also teach the steps of actuating means for positioning a light source on the surface of the platform and having photodetectors to optimally detect optical absorbance/transmittance or other optical signals, which are processed and translated into data including the number of cells on the platform (directing and then detecting a beam of electromagnetic radiation formed after interacting with the disc at the capture zone, converting the detected beam into an output signal; and analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone) (column 21, lines 57-67).

In regards to claim 2, Sheppard, Jr. et al teach that the platform surface (chamber with the disc surface) is internal to the disc and is enclosed by a top layer (cap) and a bottom layer (substrate) in Figures 5A-E. In reference to the figures, the focus of the light from the light source 54 is on the surface of the chamber where the cells are located (column 14, lines 39-58), and therefore the surface can be considered

as part of the substrate, indicated above as the bottom layer. The top layer can be considered a cap since it is superior to the chamber space and opposite the substrate.

In regards to claim 3, Sheppard, Jr. et al teach that platforms (disc) can comprise a reflective surface and the detector and the light source are positioned on the same side of the platform (column 24, lines 28-31). A reflective surface inherently reflects light if the light is not attenuated or absorbed by a substance, including a cell. Therefore, although the reference does not teach the method where light directed to the capture zone and not striking a cell is reflected, it is obvious and well known to those of ordinary skill in the art to recognize that a reflective surface will reflect light that is not attenuated or absorbed.

In regards to claim 4, Sheppard, Jr. et al teach that platforms (disc) can comprise an optically transparent surface that permits a direct light path through the surface of the platform (transmitted through the optical disc) where the light source and detector are positioned on opposite sides of the platform (column 24, lines 20-26). A transparent surface inherently transmits light through the surface if the light is not attenuated or absorbed by a substance, including a cell. Therefore, although the reference does not teach the method where light directed to the capture zone and not striking a cell is transmitted, it is obvious and well known to those of ordinary skill in the art to recognize that a transparent surface will transmit light that is not attenuated or absorbed.

In regards to claim 5, Sheppard, Jr. et al teach that specific binding reagents (cell capture agents) comprising a first member of a specific binding pair is provided coating a surface or detection chamber of a platform (column 10, lines 46-48)

Also, in regards to claim 6, Sheppard, Jr. et al teach that the surface or detection chamber can be treated to provide a two-dimensional array or pattern, wherein certain areas on the surface or detection chamber (discrete capture zone) are treated with a specific binding reagent (cell capture agents) and others (column 10, lines 60-63).

In regards to claim 7, Sheppard, Jr. et al teach that each of a multiplicity of specific binding reagents (cell capture agents) of distinct specificity are applied to different areas or regions of a surface or detection chamber of a platform of the invention (second discrete capture zones), thereby providing a pattern of such distinct specific binding reagents (predetermined pattern) on the platform (column 11, lines 5-9).

In regards to claim 8, Sheppard, Jr. et al teach that a multiplicity of specific binding reagents of distinct specificity are applied to different areas or regions (first and second capture zones) of a surface or detection chamber (column 11, lines 5-7).

In regards to claim 9, Sheppard, Jr. et al teach that specific binding reagents (cell capture agents) coated to a surface or detection chamber of a platform is intended to detect a cell expressing a cognate antigen (cell surface antigen) (column 10, lines 45-50).

In regards to claim 12, Sheppard, Jr. et al teach that the sample is driven into the binding/detection chamber and contacts the surface coated with the specific binding reagent (directing cells into proximity with cell capture agents), the sample is incubated in the chamber (incubating the cells in the presence of cell capture agents), and cells are bound to the chamber (allowing cells to bind to capture agents) (column 34, lines 29-45).

In regards to claim 13, Sheppard, Jr. et al teach visually observing the number of cells bound to the chamber (analyzing the number of cells captured) (column 34, lines 44-45).

In regards to claim 14, Sheppard, Jr. et al teach that particles adsorbed to the surface of the waveguide (disc) will both scatter and absorb light, and that the amount of radiation transmitted to the detector that is depressed relative to clean waveguides (changes in level of light reflected or transmitted through disc) can be used to infer the number of adsorbed particles (analyzing) (column 23, lines 15-20).

In regards to claims 15 and 21, Sheppard, Jr. et al teach that visual inspection of the reaction chamber can be used to resolve cells (captured cells) by a computer-aided vision system (image recognition) (column 32, lines 30-35) and that preferred embodiments include detecting and quantitating individual particles, preferably cells (counting captured cells) (column 32, lines 40-43).

In regards to claim 17, Sheppard, Jr. et al teach that arrays (capture zones) can be discrete arrays each comprising a different specific binding reagent (column 11, lines 9-12).

In regards to claim 18, Sheppard et al teach that the rotation speed of the invention is increased to drive a milk sample into the binding/detection chamber, where it contacts the surface coated with the specific binding reagent (bind with the capture molecules) and the sample is incubated in the chamber for 30 minutes (sufficient period of time) (column 34, lines 29-32). In addition, Sheppard et al teach that following incubation, the rotation rate is “increased” (column 34, line 35), which inherently implies

that there was rotation (speed) during the incubation period and therefore, the rotation period during the 30 minutes incubation was to apply a sufficient period of time at a sufficient speed so that the cells have an opportunity to bind with the capture molecules.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Chupp et al (USP 5,812, 419).

Sheppard, Jr. et al reference has been disclosed above, but fail to teach the methods of binding cell surface antigen from the CD family and specifically, binding the cell surface antigens CD3, CD4, CD8, and CD45.

Chupp et al teach a method of analyzing a blood sample to detect the presence of white blood cells with CD3 and CD8 antigen markers (columns 69-70, Example 6B), and white blood cells with CD4 and CD45 antigen markers (columns 68-69, Example 6A) to measure the fraction of lymphocytes that are T Suppressor cells and T Helper cells, respectively.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Sheppard, Jr. et al, the method of binding CD3, CD4, CD8, and CD45 cell surface antigens, as taught by Chupp et al, in order to measure the fraction of lymphocytes in a sample that are T Suppressor cells and T Helper cells, respectively.

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard, Jr. et al (USP 6,143,247) in view of Miller et al (USP 4,307,367).

15. Sheppard et al reference has been disclosed above, but fail to teach the method of using image recognition to distinguish one type of white blood cell from another.

16. Miller et al teach that pattern recognition (image recognition) can be used to determine a white blood cell differential count which detects cell types (distinguishes one type of white blood cell from another) (column 1, lines 25-29) to determine the health of a person whose blood sample is being examined.

17. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Sheppard, Jr. et al, the method of using image recognition to determine a white blood cell differential count which detects cell types in order to determine the health of a person whose blood sample is being examined.

18. Claims 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al (USP 6,143,247).

Sheppard et al reference has been disclosed above and additionally teaches increasing the rotation rate (sufficient speed) after incubation so that a wash buffer flushes the milk sample out of the chamber and into the waste receptacle (unbound cells moved away from the capture zone) (column 34, lines 32-37), but fail to teach the methods of rotating for a sufficient period of time to move unbound cells away from the capture zone and that the rotation is performed at a single speed.

A certain time period of rotation is obviously required in order to completely remove unwanted materials, including unbound cells, from the capture zone since instantaneous removal is not technically possible. In order to retain only bound cells for analysis, it is therefore necessary to rotate the disc at a certain speed for a "sufficient period of time" and this step would have been obvious and well known to a person of ordinary skill in the art at the time of the invention.

In addition, a high rate of rotation would be effective in removing all liquid samples, including unbound cells from the capture zones. This method of applying

centrifugal force is well known to those of ordinary skill in the art at the time of the invention. If the rotation were performed at a single rate high enough to remove liquids of any viscosity, it would be sufficient to remove unbound cells from the capture zone. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to perform the rotation at a single speed in order to remove all unbound cells away from the capture zone, provided that the speed is high enough to overcome resistance by the viscosity of the liquid.

19. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al (USP 6, 143, 247) in view of Sizto et al (USP 5, 962, 238).

Sheppard et al reference is disclosed above, but fail to teach a method of providing an output that includes the counts for CD4 and CD8 cells, and a ratio of CD4 to CD8 cells.

Sizto et al teach a method cell counting and classification that includes using the techniques to identify the number of cells by detecting CD4 and CD8 antigens and to obtain CD4/CD T-cell ratios (column 6, lines 17-33) to determine cells within a particular subclass that are present in a sample.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include in the method of Sheppard et al, the method of having an output to identify the number of cells by detecting CD4 and CD8 antigens and to obtain CD4/CD T-cell ratios, as taught by Sizto et al, to determine cells within a particular subclass that are present in a sample.

Double Patenting

20. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

21. Claim 1 is provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of copending Application No. 10/233322. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

22. Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-11 of copending Application No. 10/230959. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

Claims 1-22 of the instant application disclose a method of conducting an assay with an optical disc and disc drive, providing a sample of cells on a disc surface in a chamber in a disc, the chamber including at least one capture zone with a capture

agent; loading the disc into an optical reader; rotating the optical disc; directing an incident beam of electromagnetic radiation to the capture zone; detecting a beam of electromagnetic radiation formed after interacting with the disc at the capture zone' converting the detected beam into an output signal; and analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone. However, claims 1-22 of the instant application do not disclose that the method is directed towards detecting blood cell analytes in biological samples.

Claims 2-11 of the copending application discloses all the steps of claim 1 of the instant application and additionally discloses the purpose of the method is for detecting blood cell analytes in biological samples (line 1 of claim 2, for example). Claim 1 of the instant application is broad since the method is directed towards an assay, which can include an assay to detect blood cell analytes in biological samples.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that claims 1-22 of the instant application encompasses all steps and limitations of claims 2-11 of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

23. Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-10 and 13-45 of copending Application No. 10/233322. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

Claims 1-22 of the instant application disclose a method of conducting an assay with an optical disc and disc drive, providing a sample of cells on a disc surface in a chamber in a disc, the chamber including at least one capture zone with a capture agent; loading the disc into an optical reader; rotating the optical disc; directing an incident beam of electromagnetic radiation to the capture zone; detecting a beam of electromagnetic radiation formed after interacting with the disc at the capture zone' converting the detected beam into an output signal; and analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone. However, claims 1-22 of the instant application do not disclose the chamber including capture zone with a capture layer assembly.

Claims 2-10 and 13-45 of the copending application disclose that the chamber includes capture zone with a capture layer assembly (line 4 of claim 2, for example). Since line 11 of claim 2, for example, refers to cells captured at the capture zone, the capture zone would include agents to capture the cells. The capture layer assembly is a section that performs a capture mechanism and since it is part of the capture zone, the capture layer assembly must include capture agents.

In addition, claims 2–10 and 13-45 of the copending application lack the step of loading the disc into an optical reader, as disclosed in claim 1 of the instant application. However, it is inherent that a disc is required to be loaded into an optical reader in order to direct and detect electromagnetic radiation as applied towards a disc, as disclosed in lines 7-9 of claim 2, for example.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that claims 2-10 and 13-45 of the copending application encompass claims 1-22 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

24. Claims 1-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 24-35, and 37-38 of copending Application No. 10/236857. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following:

Claims 1-22 of the instant application disclose a method of conducting an assay with an optical disc and disc drive, providing a sample of cells on a disc surface in a chamber in a disc, the chamber including at least one capture zone with a capture agent; loading the disc into an optical reader; rotating the optical disc; directing an incident beam of electromagnetic radiation to the capture zone; detecting a beam of electromagnetic radiation formed after interacting with the disc at the capture zone' converting the detected beam into an output signal; and analyzing the output signal to extract therefrom information relating to the number of cells captured at the capture zone. However, claim 1 of the instant application does not disclose the step of analyzing the type of cells captured at the capture zone.

Claims 1, 24-35, and 37-38 of the copending application discloses all the steps of claim 1 of the instant application and additionally discloses the step of analyzing the

output signal to extract information relating to the type of cells captured at the capture zone (lines 11-12 of claim 1, for example).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that claims 1, 24-35, and 37-38 of the copending application encompasses all steps and limitations of claims 1-22 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

25. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Gustafson et al (USP 5,413,939) teach an assay system that uses optical detection methods to determine and measure analytes bound on a spinning disc.

Gordon (USP 5,892,577) teaches a method and apparatus for optically determining the quantity of a material bound to a rotatable disc.

Wang et al (USP 5,922,617) teach a assay methods and apparatus for screening bound components on disks.

Virtanen (USP 6,030,581) teaches an apparatus including an optical disk to assay for analytes through binding techniques.

Kellogg et al (USP 6,063,589) teach methods and apparatus for performing assays, including immunoassays, using microfluidics on a rotating disc.

Schoentag et al (American Journal of Clinical Pathology (1979) 71:685-694) teach the method of using image (pattern) recognition in an automated blood smear analyzer to count and distinguish between different types of white blood cells.

26. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y Lum whose telephone number is (571) 272-2878. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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